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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/701,979 | 02/12/2001 | Parula Mchta | 98,375-C | 1569 |

20306 7590 07/27/2004

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| EXAMINER |
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LUCAS, ZACHARIAH

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| ART UNIT | PAPER NUMBER |
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1648

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/701,979 | Applicant(s) MEHTA ET AL. | |
| | Examiner Zachariah Lucas | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1, 2, and 4-13 are pending and under consideration. These claims were rejected in the Office action mailed on November 18, 2003 (the prior action). The Applicant submitted a Response to that action May 10, 2004. No claim amendments were presented.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **(Prior Rejection- Maintained)** Claims 1, 2, and 4-13 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over McCormick (U.S. Patent 3,431,886) in view of Copeland (U.S. Patent 5,650,327), and in view of McManus et al. (Staining Methods, Histologic and Histochemical, Paul B. Hoeber, Inc., New York, 1960) and Stokes et al. (U.S. 5,318,795). The claims read on automated methods of staining biological materials on a slide comprising providing a first and second unstable solution, and providing a slide with a biological material to be stained, and sequentially applying the first and second solutions to the material such that an unstable solution is formed in contact with the material.

The Applicant traverses the rejection on two grounds. First, the Applicant argues that the Examiner has incorrectly interpreted the teachings of the Stokes reference. In particular, the Applicant argues that, because the reference does not specifically teach the claimed embodiments, then the reference cannot describe the combination of multiple reagents to make a stain. This argument is not found persuasive. It is first noted that the Stokes reference is not the sole reference cited in the rejection. As was described in the prior actions, the Stokes reference teaches that stains may be added in a step, but that a step does not require the addition of only a single reagent in each step. Thus, the reference is clearly not limited to embodiments where only pre-mixed stains are added to a sample. These teachings, in addition to the understanding of the term “reagent” in the art, and the knowledge in the art regarding the use of unstable stains made from a combination of stable reagents (as exemplified in McManus), render the claims obvious.

The second ground of traversal is that the Examiner has applied improper hindsight to the rejection of the claimed invention. In particular, the Applicant argues that the prior art does not teach that the stable ingredients of the unstable solution may be applied “independently and before mixing” to the sample, and that there is no support in the prior art for reading the term “reagent” as encompassing individual ingredients useful to form a useful solution. These arguments are not found persuasive. First, the rejection is not relying on any teachings to add the ingredients “independently and before mixing” to the sample. Rather, as indicated in the prior action (see pages 3-4) the art teaches the Stokes reference indicates that multiple reagents may be simultaneously applied, that the mode of application described therein results in the mixing of the solution on the sample. See e.g., Copeland, column 4 (teaching automated methods comprising a step of applying a reagent staining solution to the slide and mixing the solution on

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the surface of the slide containing the tissue by applying a gas stream or two gas streams so as to form a vortex). Thus, the Applicant's first ground of asserting the use of improper hindsight is not found persuasive.

The second grounds, that there is not support for the Examiner's interpretation of the term "reagent" is also not found persuasive. In particular, the Applicant's attention is drawn to page 5 of the prior action, citing support for the interpretation. It is further noted that the Applicant has provided no evidence that this is not a reasonable interpretation of the term. In such instances, the unsupported arguments of an Applicant are not afforded the weight of actual evidence. See e.g., MPEP 716.01(c). For these reasons, and for the reasons of record, Applicant's arguments are not found persuasive, and the rejection is maintained.

Conclusion

4. No claims are allowed.
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

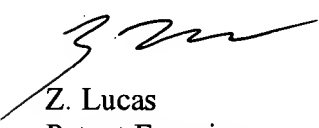
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



7/26/04
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600